

Docket No.: NY-MSI 203-US
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Edward F. Ikeguchi et al.

Application No.: 10/667,848

Confirmation No.: 1385

Filed: September 22, 2003

Art Unit: N/A

For: SYSTEM AND METHOD FOR
CONTINUOUS DATA ANALYSIS OF
AN ONGOING CLINICAL TRIAL

Examiner: Not Yet Assigned

SECOND
INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 C.F.R. § 1.97(b)(3)).

A copy of only those references listed below is attached:

| Other Documents |
|--|
| VANGENEUGDEN et al., "Applying Concepts of Generalizability Theory on Clinical Trial Data to Investigate Sources of Variation and Their Impact on Reliability," BIOMETRICS, 61, 295-304 (March 2005) |
| SHANKAR et al., "Epoch: an Ontological Framework to Support Clinical Trials Management," Conference on Information and Knowledge Management, 23-32 (2006) |
| RAO et al., "Clinical and Financial Outcomes Analysis with Existing Hospital Patient Records," Conference on Knowledge Discovery in Data, 416-425 (2003) |
| SHANKAR et al., "A Knowledge-Based System for Managing Complex Clinical Trials," Computer-Based Medical Systems, 2006, CBMS 2006., 19th IEEE International Symposium, 270-278, (June 22-23, 2006) |
| TRAHER et al., "Clinical Trial Remote Data Capture Client/Server Solution," Conference on Object Oriented Programming Systems Languages and Applications, 175-176 (2000) |
| ANDERSON et al., "SCIENTIFIC INFORMATION RETRIEVAL SYSTEM: A NEW APPROACH TO RESEARCH DATA MANAGEMENT," User Services Conference, 209-212 (1977) |

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56(a) exists. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0624, under Order No. NY-MSI 203-US (10406788).

Respectfully submitted,

By 

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Registration No.: 40,657

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Attorney Docket No.: NY-MSI 203-US



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Fani Malikouzakis

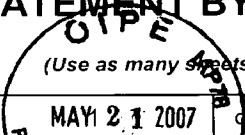
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IDS (Citation) by Applicant (28 References) (2 pages)
Second Information Disclosure Statement (2 pages)
Copies of Non-US Literature

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| Substitute for form 1449/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT  | | Application Number | 10/667,848-Conf. #1385 |
| | | Filing Date | September 22, 2003 |
| | | First Named Inventor | Edward F. Ikeguchi |
| | | Art Unit | N/A |
| | | Examiner Name | Not Yet Assigned |
| Sheet | 2 | Attorney Docket Number | NY-MSI 203-US |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| /R.R./ | AA* | US-2006/0129326-A1 | 06-15-2006 | BRACONNIER et al. | |
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| | AS* | US-2003/0104453-A1 | 06-05-2003 | PICKAR et al. | |
| | AT* | US-2003/0065535-A1 | 04-03-2003 | KARLOV et al. | |
| /R.R./ | AU* | US-2002/0183965-A1 | 12-05-2002 | GOGOLAK | |
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| FOREIGN PATENT DOCUMENTS | | | | | | |
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| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| /R.R./ | CA | VANGENEUGDEN et al., "Applying Concepts of Generalizability Theory on Clinical Trial Data to Investigate Sources of Variation and Their Impact on Reliability," BIOMETRICS, 61, 295-304 (March 2005) | |

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|--------------------|--------------------------|-----------------|------------|
| Examiner Signature | /Rajiv Raj/ (02/05/2008) | Date Considered | 02/05/2008 |
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| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/667,848-Conf. #1385 |
| | | | | Filing Date | September 22, 2003 |
| | | | | First Named Inventor | Edward F. Ikeguchi |
| | | | | Art Unit | N/A |
| | | | | Examiner Name | Not Yet Assigned |
| Sheet | 2 | of | 2 | Attorney Docket Number | NY-MSI 203-US |

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| | CC | RAO et al., "Clinical and Financial Outcomes Analysis with Existing Hospital Patient Records," Conference on Knowledge Discovery in Data, 416-425 (2003) | |
| | CD | SHANKAR et al., "A Knowledge-Based System for Managing Complex Clinical Trials," Computer-Based Medical Systems, 2006, CBMS 2006., 19th IEEE International Symposium, 270-278, (June 22-23, 2006) | |
| | CE | TRAHER et al., "Clinical Trial Remote Data Capture Client/Server Solution," Conference on Object Oriented Programming Systems Languages and Applications, 175-176 (2000) | |
| /R.R./ | CF | ANDERSON et al., "SCIENTIFIC INFORMATION RETRIEVAL SYSTEM: A NEW APPROACH TO RESEARCH DATA MANAGEMENT," User Services Conference, 209-212 (1977) | |

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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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|--------------------|--------------------------|-----------------|------------|
| Examiner Signature | /Rajiv Raj/ (02/05/2008) | Date Considered | 02/05/2008 |
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